

Modern Cementing Technique

Biomet Bone Cement R, Refobacin® Bone Cement R,
and ClearMix™ Vacuum Mixing System



Modern Cementing Technique (MCT) for improved clinical outcome^{1,2}

Modern Cementing Technique Knee (MCT Knee) addresses implant loosening and the objective is to provide long term implant stability in knee arthroplasty. It is based on scientific data,^{1-26*} findings by Zimmer Biomet²⁷ and evidence-based techniques documented in the Swedish Hip Arthroplasty Register.^{1,2}

The crucial factors in knee arthroplasty to achieve long term implant stability are to secure a strong bond and optimal interfaces, both between implant-cement and cement-bone.

Implant-Cement Interface

- Deliver the cement with a cement gun, and appropriate delivery devices, such as knee nozzles
- Apply bone cement to implant first, as early as possible in the sticky phase^{4,27}
- Prevent implant-cement interface contamination by implementing a “no-touch” policy^{4,27}

Bone Cement

- Use a bone cement with good mechanical and consistent handling properties
- Mix and collect the cement under vacuum to reduce cement porosity and to improve mechanical strength^{8,28*}

Cement-Bone Interface

- Perforate cancellous bone if dense or sclerotic²⁴
- Clean with high pressure pulsatile lavage repeatedly until clear fluid is received in the return line²⁹⁻³¹
- Deliver the cement with a cement gun and appropriate delivery devices, such as knee nozzles
- Deliver bone cement into tibial stem hole to achieve full cementation²¹⁻²³

Implant-Cement Interface

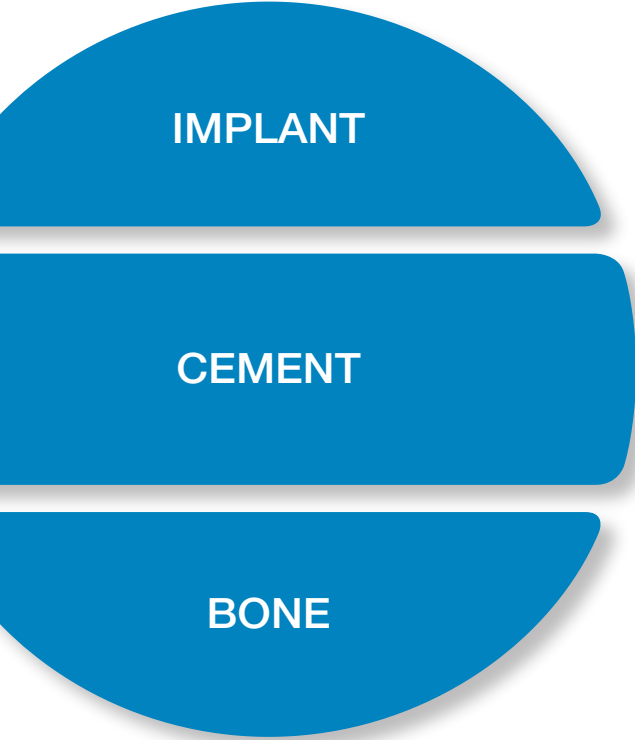
Bone Cement

Cement-Bone Interface



*Bench test results not necessarily indicative of clinical performance.

Help to secure a strong bond and optimal interfaces between Implant-Cement and Cement-Bone



Modern Cementing Technique Key Steps

Bone Bed Preparation

Cleanse all cement-receiving bone surfaces thoroughly using high pressure pulse lavage of the entire resected bone surface in order to ensure solid cement fixation.²⁹⁻³¹

Clean repeatedly until clear fluid is received in the return line to reduce the amount of debris, blood, bacteria and fat.²⁹⁻³¹

Tibia

In sclerotic bone, supplementary anchorage holes may increase the contact area between bone and cement, providing enhanced fixation.

Curette cysts and remove pericystic sclerotic walls. Depending on cyst diameter, patient age and activity level, fill bone defects with bone cement or particulate bone graft.

Femur

Contained defects can be grafted with bone taken from the cut surfaces.³²

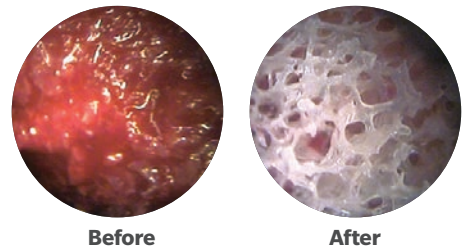
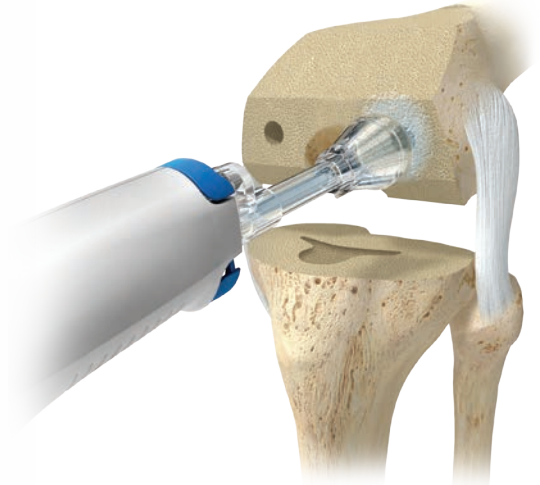
In sclerotic bone, drill supplementary anchorage holes.

Perform thorough pulsatile lavage of all surfaces.

Before cement application, bone surfaces should be kept dry, including the posterior aspect of the femoral condyles.

Patella

If the resected bone surface is hard and sclerotic, supplementary anchorage holes may be drilled.



Vacuum Mixing of Bone Cement

Mix cement in a closed vacuum mixing system to reduce micro and macro pores and decrease the risk of cracks in the cement.^{5,7,9,33}

The handling properties of the bone cement are highly dependent on the temperatures of the cement and the operating room. Higher temperatures make for a shorter sticky and dough phases and a faster setting time.

High viscosity bone cement like Biomet Bone Cement R and Refobacin® Bone Cement R can be pre-chilled if a longer sticky and dough phase is required.

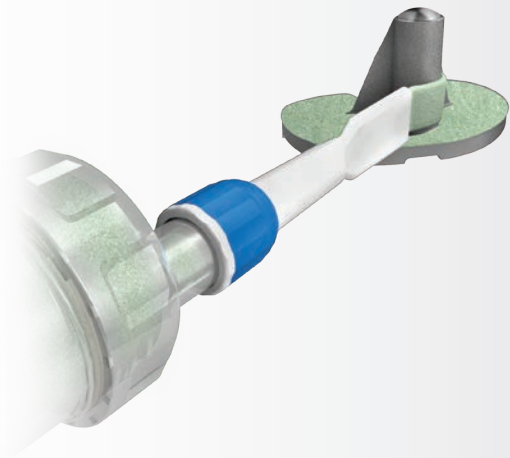
⊖ **Note:** Inclusions of blood and laminations in the cement mass reduces the mechanical strength of the resulting cement mantle.^{34,35}

Delivery and Pressurization of Bone Cement on Implant

Start with applying the bone cement on implant as early as possible in the sticky phase.

Deliver the cement with a cement gun. Use the flat knee nozzle and apply the sticky bone cement to the implant.

Prevent implant-cement interface contamination by implementing a “no-touch” policy.



Implanting Final Components

The components may be cemented sequentially or simultaneously.

Tibia

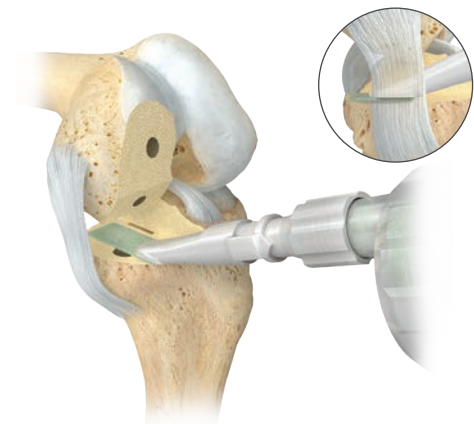
Delivery and Pressurization of Bone Cement on Bone

Deliver the cement to a clean, dry bone bed following pulse lavage.

Use a cement gun and an adequate nozzle in order to minimize the risk of air and blood entrapment and achieve sufficient pressurization. Apply cement on bone and pressurize the cement, striving for penetration of 3-4 mm to help ensure optimal fixation and stress distribution.



Total Knee Replacement



Partial Knee Replacement

Insertion Components

To facilitate insertion, flex the knee and externally rotate the tibia. Press down on the posterior portion of the tibial component first to force excess cement anteriorly. Then press down on the anterior portion of the component with the impactor pad assembled to the Tibial Plate Impactor. Impact the tibial base plate moving from posterior to anterior until fully seated.



Remove any excess cement from posterior aspect of the tibia using a curved tonsile/ hemostat.

Femur

Delivery and Pressurization of Bone Cement on Bone

Deliver the cement to a clean, dry bone bed following pulse lavage.

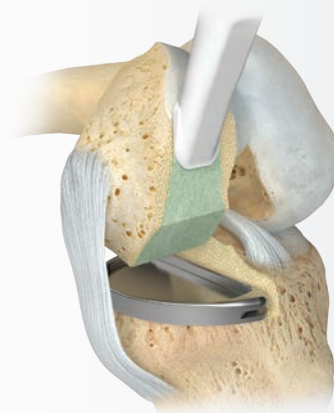
Apply a layer of cement over the entire bone-opposing surface of the femoral component using a cement gun and an appropriate nozzle.

Pressurize the cement, striving for penetration of 3-4 mm to help ensure optimal fixation and stress distribution.

Avoid contamination of the implant-cement interface.



Total Knee Replacement



Partial Knee Replacement

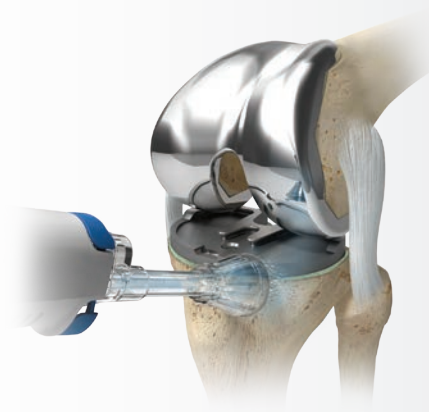
Insertion Components

The components are inserted and driven into position with impactors, followed by trial liner insertion and compression with the leg lift method.



After polymerization remaining cement at implant peripheries are removed.

Cement debris is removed by high pressure pulse lavage.

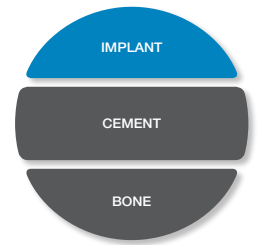


Implant - Cement Interface

General Clinical Problem in Knee Arthroplasty: Tibial Loosening

Tibial loosening between cement and implant is not limited to any particular cement brand or tibial component design. The overriding factor is the cementation technique.^{4*}

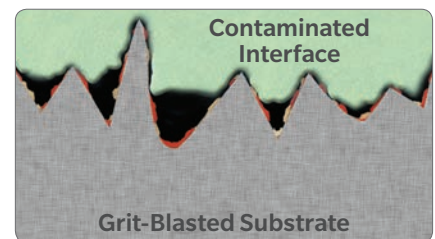
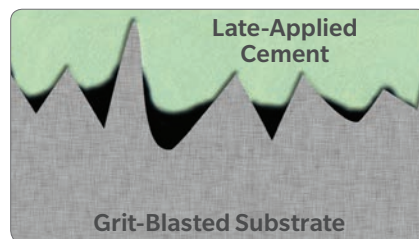
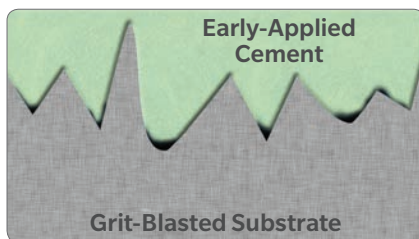
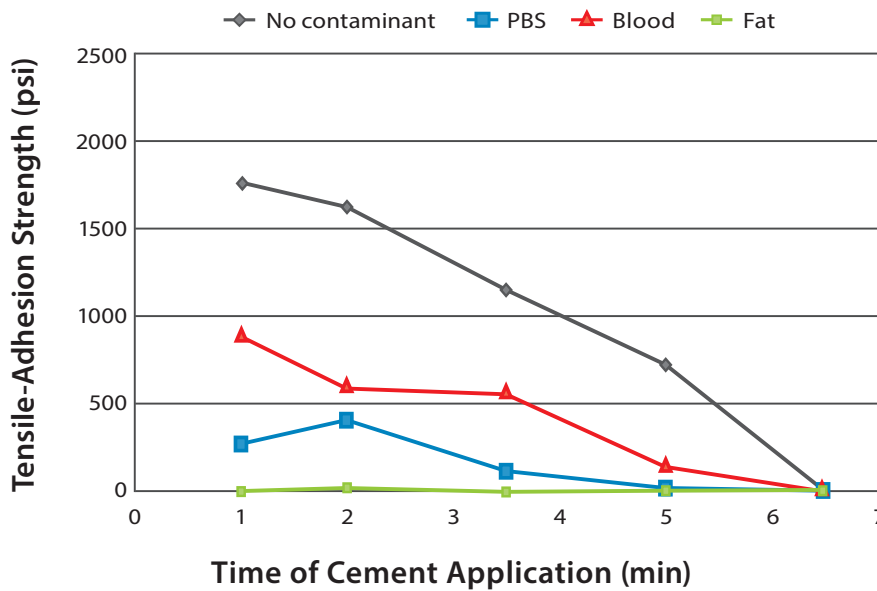
- Knee revisions in US 2017 were projected to be 94,500 with an annual growth rate of 6.2%³⁶
- Aseptic loosening of cemented tibial components remain a major cause of failure. It is shown in literature to account for 24% of all knee revisions³
- Micro motion at the implant-cement or cement-bone interface can generate wear particles³⁷



Fixation - Cement Application

Optimized micro-mechanical interlock can be achieved with early applied sticky bone cement to a non-contaminated implant surface.^{27*}

Tensile-Adhesion Strength of Biomet Bone Cement R on 30 grit blast CoCr^{27*}



*Lab test results not necessarily indicative of clinical performance.

Implant - Cement Interface

Independent Study with Stryker Triathlon® Tibial Trays and Simplex® and PALACOS® Bone Cements^{4*}

Conclusions

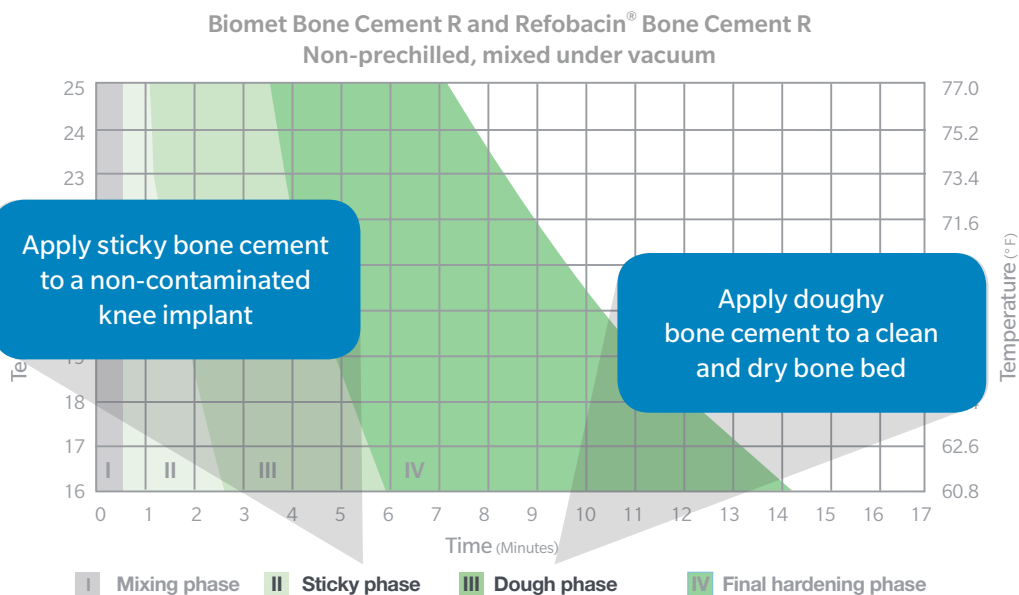
- Under laboratory conditions, a clean tibial tray-cement interface is strong, but much stronger when the keel is cemented
- Earlier application of the cement to metal increases bond strength while later application reduces bond strength
- Fat contamination of the tibial tray-cement interface reduces bond strength, but application of cement to the underside of the tibial tray prior to insertion substantially mitigates this

Solutions for Modern Cementing Technique Knee

Deliver the cement with a cement gun and appropriate delivery devices, as applicable. Use the flat knee nozzle and apply the bone cement to implant first, as early as possible in the sticky phase.

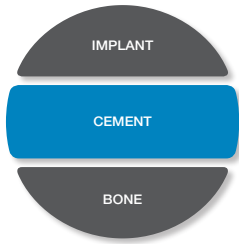


Flat Knee Nozzle used for early application on implant



*Lab test results not necessarily indicative of clinical performance.

Bone Cement



Bone Cement

Polymethyl methacrylate (PMMA) bone cements fill the space between prostheses and bone, transmitting and evenly distributing loads. The main considerations are:

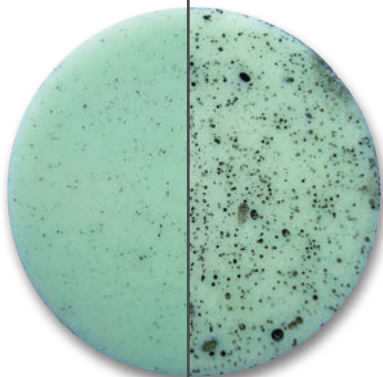
- Good mechanical properties
- Consistent handling properties

Mixing Under Vacuum

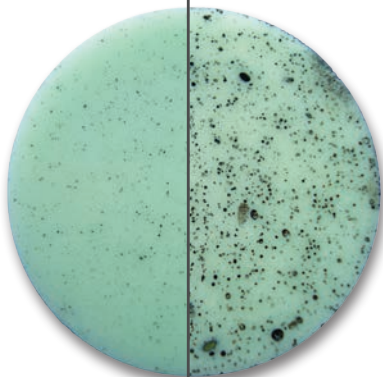
Mixing under vacuum reduces both micro and macro pores.^{8*} Deliver the cement with a cement gun and nozzle suitable for the application.¹⁰

- Improved cement strength and fatigue life⁷
- Lower risk of aseptic loosening due to cracks in the cement^{7-10*}
- Delivery of reproducible results
- Less exposure to monomer fumes^{11*}

Cement mixed under vacuum^{28*}



Cement mixed at atmospheric pressure^{28*}



* Lab test results not necessarily indicative of clinical performance.

Cement - Bone Interface

Bone Bed Preparation

Preparation of the bone bed with a pulsative lavage system, like the Pulsavac® Plus Wound Debridement System, helps to ensure solid cement fixation. Clean repeatedly until clear fluid is received in the return line to reduce the amount of debris, blood, bacteria and fat.²⁹⁻³¹

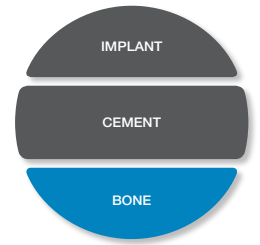
- To obtain proper cement penetration and fixation into the cancellous bone³⁸
- Reduce the risk for revision due to aseptic loosening^{3,18}
- Reduce the risk for fat embolism²⁹

Delivery

- A uniform, deep bone cement mantle provides for optimal fixation and stress distribution^{14*,15}
- Application with a cement gun and an appropriate nozzle on both tibia and femur¹⁶⁻¹⁹
- Delivery to a clean, dry bone bed following pulse lavage⁷

Pressurization

- Increases penetration into the cancellous bone²⁰
- Improves interface between bone and cement^{7*}



23 Degree Pressurizing Nozzle used to apply bone cement and pressurize

* Lab test results not necessarily indicative of clinical performance.

Biomet Bone Cement R and Refobacin® Bone Cement R

Reliable performance

Zimmer Biomet's bone cements follow the standard specifications in all respects of material used, formulation and manufacturing methods. Bone cements from Zimmer Biomet show reliable performance based on international laboratory standard testing.^{39,40}

Easy handling

Biomet Bone Cement R and Refobacin® Bone Cement R can be mixed both by hand and in a vacuum mixing system. However, Modern Cementing Technique recommends using a vacuum mixing system such as the ClearMix™ Vacuum Mixers for mixing and delivery of bone cement. This makes standardized handling easy and helps achieve a reproducible, homogeneous bone cement of the highest quality.^{10,41}

Antibiotic-loaded cement - broad antibacterial spectrum

Gentamicin has proven to be the antibiotic of choice for bone cement due to its broad antibacterial coverage.⁴³ Refobacin® Bone Cement R includes 0.5g active gentamicin and provides high local concentrations of gentamicin over several days.⁴⁴ The protracted release of the antibiotics may protect the implant for an extended period of time, thus reducing the risk of revision.⁴⁵

High visibility

Biomet Bone Cement R and Refobacin® Bone Cement R contain chlorophyll and the green coloring improves visualization to surrounding tissue. These cements also provide excellent visualization under post-op x-ray.



ClearMix Vacuum Mixing System

High quality vacuum mixing

ClearMix is a high performing vacuum cartridge mixing and delivery system. It allows for a standardized mixing procedure when cement is mixed, resulting in a high quality bone cement. This vacuum mixing system can be used to mix all viscosities of PMMA bone cement.

Practical and easy to use

This easy to use system requires minimal assembly. The mixing rod has a colored indicator that identifies the snap point for breaking. In addition, the vacuum line is equipped with a visual vacuum indicator to ensure proper vacuum level is present before mixing.

Safer working environment

ClearMix Vacuum Mixing System meets modern safety standards and the high demands on mixing bone cement in the OR. By drawing the monomer fumes through special filters, the ClearMix System minimizes MMA exposure of the OR staff to a level significantly lower than OSHA and NIOSH guidelines.²⁷

Clear viewing

Based on customer feedback, the clear tube is important as it allows them to see the bone cement during the mixing process.



ClearMix Vacuum Mixing System

ClearMix Vacuum Mixing System is available in two different sizes

The ClearMix Vacuum Mixing System is available as single/double for 40-80g bone cement and as triple for 120g bone cement.

Knee nozzles for improved cement interfaces

Zimmer Biomet provides knee nozzles for optimal delivery and pressurization of the bone cement.



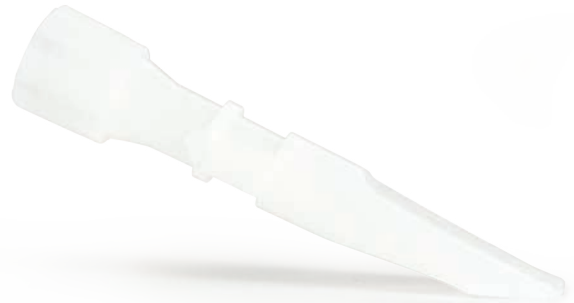
ClearMix Vacuum Mixing System
40-80g bone cement



ClearMix Triple Vacuum Mixing System
120g bone cement



Nozzle Knee Flat





23-Degree Pressurizing Nozzle










Knee Cementation Nozzle

Ordering Information

| Product | Part Number | Description | Units/Case |
|---|-------------|--|------------|
|  | 110035368 | Biomet Bone Cement R 1X40 | 1 |
|  | 110034355 | Refobacin® Bone Cement R 1X40 (with Gentamicin) | 1 |

Bone Cement Mixing Systems

| Product | Part Number | Description | Units/Case |
|---|-------------|--|------------|
|  | 414701 | ClearMix Single/Double | 1 |
| | 414702 | ClearMix Single/Double | 10 |
|  | 414703 | ClearMix Triple | 1 |
|  | 4146 | Nozzle Knee Flat | 5 |
|  | 110031498 | 23-Degree Pressurizing Nozzle and Knee Cementation Nozzle | 5 |
|  | 414700 | ClearMix Delivery Gun | 1 |
|  | 00504905300 | Quik-Use® Curette | 10 |
|  | 00504908600 | Zimmer® Vacuum Foot Pump II-Air Connector | 1 |

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